UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	)	
	)	
This document relates to:	)	MDL 2804
	)	
City of Cleveland, et al. v. Purdue Pharma L.P., et al., Case No. 18-OP-45132;	)	Case No. 17-md-2804
	)	Hon. Dan Aaron Polster
	)	Mag. Judge David A. Ruiz
County of Cuyahoga, et al. v. Purdue Pharma L.P., et al., Case No. 17-OP-45004;	)	
	)	
	)	
County of Summit, et al. v. Purdue Pharma, L.P. et al., Case No. 18-OP-45090	)	
	)	

EXPERT REPORT OF WILLIAM S. CHOI, PH.D.

May 10, 2019

I.   Introduction

1.   I have been retained by the CVS defendants in the MDL Track 1 cases, namely CVS Indiana, L.L.C. and CVS Rx Services, Inc. ("CVS"),[1] through its counsel Zuckerman Spaeder LLP to review and respond to the analysis of distributors' suspicious order monitoring ("SOM"), as well as other economic, and statistical analyses presented in a number of reports that were submitted on behalf of the Counties of Cuyahoga and Summit (collectively, "Bellwether governments" or "Plaintiffs"). Specifically, I have reviewed the expert reports submitted by David Cutler,[2] Craig McCann,[3] James Rafalski,[4] and Seth Whitelaw.[5] I have been asked to evaluate, from a statistical standpoint and from the standpoint of accepted methods for calculating economic damages, Plaintiffs' but-for analysis of distributors' SOM procedures as discussed in the reports of Prof. Cutler,

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[1] I am informed by counsel that CVS Indiana, LLC and CVS Rx Services, Inc. are the named CVS defendants in the MDL Track 1 cases and own distribution centers that distributed certain prescription drugs to CVS retail pharmacies in Cuyahoga and Summit counties.

[2] "Expert Report of Professor David Cutler," dated March 25, 2019 ("Cutler Report").

[3] "Expert Report of Craig J. McCann, Ph.D., CFA," dated March 25, 2019 ("McCann Report") and "Supplemental Expert Report of Craig J. McCann, Ph.D., CFA," dated April 3, 2019 ("McCann Supplemental Report").

[4] "Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances," dated April 15, 2019 ("Rafalski Report").

[5] "Examination of Compliance Standards for Opioid Manufacturers and Distributors," dated April 15, 2019 ("Whitelaw Report").

Dr. McCann, Mr. Rafalski, and Mr. Whitelaw, as well as CVS's SOM procedures during the period of this litigation.

2.   The identified Plaintiffs' expert reports that I have reviewed are based on the unsupported assumption that distributors should have recognized and curtailed shipments using particular SOM methodologies described in the McCann Report. However, the SOM methodologies, as applied by Dr. McCann, are arbitrary and produce implausible results. As an example, Dr. McCann's SOM methodologies assume that CVS (and other distributors) would have implemented an unrealistic process where either no orders are evaluated or all orders are evaluated. Furthermore, Prof. Cutler's interpretation and use of these SOM methodologies would imply that some pharmacies would have received no shipments of opioids for most of the relevant period in this matter, while other pharmacies would have received all of their actual orders. These scenarios are implausible and inconsistent with what I understand is the Drug Enforcement Administration's ("DEA") mandate to distributors. It also is inconsistent with my understanding that these are shipments of legitimate medicines and not presumptively improper. A SOM method that results in no orders being shipped to a pharmacy for an extended period of time does not reconcile with a credible but-for scenario. An estimate of damages caused by the alleged misconduct needs to be based on "a description of the defendant's proper actions in place of its unlawful actions and a statement about the economic situation absent the wrongdoing, with the defendant's proper actions replacing the unlawful ones (the but-for scenario)."[6]

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[6] Allen, Mark. A., R.E. Hall, and V.A. Lazear. "Reference Guide on Estimation of Economic Damages" in *Reference Manual on Scientific Evidence,* 3rd ed. Federal Judicial Center, 2011, p.432.

3.   In reality, CVS had in place SOM programs, which flagged potentially suspicious orders and had a process to evaluate those flagged orders. From 2009 to 2014, CVS adopted and evolved an approach that utilized a modified logit regression model to identify potentially suspicious orders ("CCS-SOM").[7] CVS subsequently replaced the CCS-SOM with an alternative algorithm ("AGI-SOM") in early 2014.[8] Both algorithms were designed to flag for further review orders that may be of unusual size, unusual frequency, and exhibiting an unusual pattern. It is my opinion that these algorithms, from a statistical standpoint, were reasonable approaches for identifying potentially suspicious orders (*i.e.*, outliers) and are consistent with my understanding of the DEA's criteria for distributors.

4.   Plaintiffs' experts have not provided a substantive critique of these algorithms nor how such algorithms would have needed to be improved to meet DEA requirements. Instead, Plaintiffs' experts have simply disregarded entirely the CVS SOMs and imposed their own extreme methodologies that are not grounded in reality nor have a statistical basis.

II.   Qualifications

5.   I am a Managing Director in the professional services firm AlixPartners, LLC ("AlixPartners").   I have extensive experience in economic, financial, and statistical

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[7] CVS-MDLT1-000123386 to CVS-MDLT1-000123392, CVS-MDLT1-000114642 to CVS-MDLT1-000114652 , and CVS-MDLT1-000109623 to CVS-MDLT1-000109625.

[8] CVS-MDLT1-000018670 to CVS-MDLT1-000018674.

analyses, and over the course of my professional career, I have worked on issues relating to the assessment of economic damages and statistical methods. I have provided consulting services to large corporations, privately held companies, and the U.S. government on issues relating to econometrics, statistics, business forecasting, intellectual property, market structure, market share, consumer class actions, pricing, structured finance, and optimal inventory.

6.   With regard to statistical and econometric methods, I have been retained by the Securities and Exchange Commission and the Department of Justice to conduct statistical analysis to assist in their respective investigations of mortgage-related fraud resulting in some of the largest settlements in U.S. history. I also have testified on several matters related to statistical and econometric methods. In addition, I have assisted companies with regression modeling, representative sampling, and forecasting across a range of industries, including sporting goods, consumer electronics, alcoholic beverages, mortgage loans, insurance claims, warranty claims, and video games. My analyses on such matters have included the examination of outliers and use of limited dependent variable models.

7.   I received my doctorate in economics from Duke University. I received from the same institution an M.A. in economics. I also received my M.A. in business economics with a concentration in managerial accounting from the University of California, Santa Barbara, and my B.S. in economics from the University of California, Riverside. I have authored articles and given presentations related to market structure, game theory, licensing, structured finance, and econometrics. **Exhibit 1** is my most recent curriculum vitae, and **Exhibit 2** identifies my litigation testimony over the past four years.

8. AlixPartners is being compensated at the rate of $970 per hour for my work in this matter. I utilized a team of AlixPartners' personnel who worked under my direction. AlixPartners is being compensated for time incurred by other professionals who have supported my analysis in this matter at $550 to $970 per hour.

9. This report is a statement of opinions I expect to express in this matter and the basis and reasons for those opinions. In forming the opinions expressed in this report I relied upon my education, experience, and knowledge of the subjects discussed. I also have relied upon a number of documents and other materials, which are cited herein or listed in **Exhibit 3**. To the extent that additional information relevant to my analysis is made available, I maintain the right to update and supplement my opinions.

III. Background

A. Allegations

10. Plaintiffs allege that the Distributor Defendants, including CVS, made "deliberate efforts to evade restrictions on opioid distribution,"[9] and that "the Distributor Defendants universally failed to comply with federal and/or state law."[10] According to Plaintiffs, the Distributor Defendants "failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and

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[9] Second Amended Corrected Complaint, ¶3.

[10] Second Amended Corrected Complaint, ¶81.

halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market."[11] As a result, Plaintiffs allege there was an overall failure by manufacturers and distributors "to maintain effective controls over distribution of prescription opioids [and instead Distributor Defendants] actively sought to evade such controls."[12]

B.   Opioids

11.   Pain affects millions of Americans, and to treat this health problem some patients are prescribed opioid painkillers.[13] While potentially addictive and prone to abuse, when used as directed, prescription opioids can be an effective treatment for acute or chronic pain conditions.[14] They provide relief for patients suffering from severe pain following surgery or trauma and for those dealing with painful terminal diseases such as cancer.[15]

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[11] Second Amended Corrected Complaint, ¶9.

[12] Second Amended Corrected Complaint, ¶14.

[13] US Government Accountability Office, "Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access." June 2015, ("GAO 2015"), p. 7.

[14] US Government Accountability Office, "Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access." June 2015, ("GAO 2015"), p. 7.

[15] GAO 2015, pp. 7-8.

12.   Oxycodone and hydrocodone are two types of prescription opioid pain relievers.[16]   Oxycodone is an effective painkiller for moderate to severe pain, and is marketed in both controlled release and immediate release formulas.[17]   It is commonly combined with non-opioid painkillers, and can be prescribed for intense pain after surgery, to treat diabetic neuropathy and is provided in higher doses for long-term intractable cancer pain.[18] In addition to being prescribed for chronic, severe pain in patients requiring long-term care, hydrocodone is also a frequent choice amongst dentists prescribing opioids for pain relief and, due to its cough suppressant properties, it is found in prescription cold and cough formulas.[19]

C.   CVS

13.   CVS Indiana, L.L.C. and CVS Rx Services, Inc. distribute products, including controlled substances and other prescription drugs, to CVS retail pharmacies ("CVS pharmacies").   CVS does not distribute products to any non-CVS owned pharmacies. Relevant to this litigation, CVS distributed until October 2014 hydrocodone combination

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[16] GAO 2015, p. 7.

[17] DEA Tearsheet: Oxycodone.

https://www.pdr.net/drug-summary/Oxycodone-Hydrochloride-Tablets-oxycodone-hydrochloride-3271

[18] DEA Tearsheet: Oxycodone.

https://www.pdr.net/drug-summary/Oxycodone-Hydrochloride-Tablets-oxycodone-hydrochloride-3271

[19] DEA Tearsheet: Hydrocodone. US National Library of Medicine Review – Hydrocodone Uses, pp. 3-4.

https://www.pdr.net/drug-summary/Hysingla-ER-hydrocodone-bitartrate-3661.

products ("HCPs") to CVS pharmacies. HCPs are medications that combine hydrocodone with other pain analgesics such as acetaminophen. CVS did not and does not distribute oxycodone, pure hydrocodone, or any Schedule II controlled substances.

D.   Diversion

14.   Plaintiffs allege that Defendants failed to "maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious [and hence] breached their statutory and common law duties."[20]   They allege that Defendants "failed to report suspicious orders, prevent diversion or otherwise control the supply of opioids."[21]

15.   The opioids at issue, including HCPs, are FDA-approved to treat certain medical conditions.[22]   At the same time, like other drugs manufactured for legitimate medical use, opioids are subject to abuse. As the DEA notes, "many problems associated with drug abuse are the result of legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic."[23]   Consequently, the Controlled Substances Act and regulations require manufacturers, distributors, and dispensers of

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[20] Second Amended Corrected Complaint, ¶466.

[21] Second Amended Corrected Complaint, ¶547.

[22] The DEA states the mission of its Diversion Control Division "is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs." (https://www.deadiversion.usdoj.gov/Inside.html)

[23] https://www.deadiversion.usdoj.gov/prog_dscrpt/index.html

controlled substances such as opioids to hold a DEA registration and to meet requirements pertaining to drug security and record keeping and reporting of controlled substance inventories and business transactions.[24]

E. DEA Guidance on Suspicious Order Monitoring

16. The Code of Federal Regulations ("CFR") requires registrants to "design and operate" a system to report suspicious orders to the DEA:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.[25]

The CFR provides the following description of suspicious orders:

> Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[26]

Similarly, the guidance provided by the DEA states that:

> The registrant must design and operate a system to disclose suspicious orders of controlled substances. The registrant must inform the appropriate DEA Field Office of suspicious orders immediately upon discovery. Such orders include, but are not limited to, *orders of unusual size, orders deviating substantially*

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[24] https://www.deadiversion.usdoj.gov/arcos/handbook/glossary.htm

[25] 21 CFR 1301.74.(b), available at https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm.

[26] 21 CFR 1301.74.(b), available at https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm.

from a normal pattern, and orders of unusual frequency.[27]
[emphasis added]

The federal regulation does not provide a quantitative definition of suspicious orders. According to Thomas Prevoznik, Acting Section Chief of Pharmaceutical Investigations in the Diversion Control Division of DEA, the DEA does not mandate any one particular method for identifying suspicious orders, nor does it mandate that such a method be automated or manual.[28]

17.   It is my understanding that many registrants now use algorithms that, in effect, detect outliers that are then evaluated to determine if they pose a risk for diversion. An algorithm, however, does not in itself determine whether an order is legitimate or likely to be diverted.

IV. CVS's SOM Systems Relied on Reasonable Statistical Methods

A.   Identifying Potentially Suspicious Orders Through Detection of Outliers

18.   Identifying potentially suspicious orders can be analogous to the statistical concept of identifying outlying observations (or "outliers"). An observation is usually deemed to be an outlier if "it deviates from the normal/known behavior of the data, it

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[27] DEA. "Controlled Substances Security Manual: Other Security Controls," available at https://www.deadiversion.usdoj.gov/pubs/manuals/sec/other_sec.htm.

[28] Deposition of Thomas Prevoznik, dated April 17th, 2019, at p. 180:3-15.

assumes values that are far away from the expected/average values, or it is not connected/similar to any other object in terms of its characteristics."[29]

19.   Detecting outliers requires distinguishing between randomness or "noise" in the data and "unusual" observations. Orders placed by pharmacies tend to exhibit a degree of volatility in terms of volume and frequency, and, consequently, identifying outlying orders requires distinguishing these from ordinary fluctuations in pharmacy ordering behavior. Moreover, once a transaction is flagged, it should be evaluated more closely to determine whether it qualifies as suspicious and should be reported.[30]

B.   CVS's Automated SOM Systems

20.   CVS has had in place different SOM methods during the relevant time period. In 2007, CVS retained BuzzeoPDMA, which was subsequently acquired by Cegedim Compliance Solutions (collectively "CCS"), to develop a procedure for complying with a variety of requirements of the CSA and regulations regarding handling of controlled substances and listed chemicals.[31] As part of its work, CCS created an algorithm ("CCS-SOM") to identify orders for further evaluation as to whether they were suspicious. The algorithm was placed in operation by CVS in late 2008 or early 2009.[32] CCS advised CVS

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[29] N. N. R Ranga Suri *et al.*, *Outlier Detection: Techniques and Applications.* Springer Nature Switzerland, 2019, p. 3.

[30] For a discussion of appropriate treatment of "unusual" or "influential" observations in econometrics, see Kennedy, P. *A Guide to Econometrics* 6th ed, Blackwell Publishing, 2008, p.347.

[31] CVS-MDLT1-000114642.

[32] CVS-MDLT1-000114642.

in connection with changes to the algorithm from time to time thereafter while the CCS-SOM was in use by CVS from 2009 to 2014. CVS implemented a new SOM computer algorithm developed with Analysis Group, Inc. ("AGI-SOM") in early 2014.[33]

C.   CVS's SOM Systems are and were Based on Reasonable Statistical Methods

a)   CCS-SOM Applies Established Statistical Tools Consistent with DEA Criteria

21.   I have reviewed the supporting documents related to the CCS-SOM.[34] The CCS-SOM is a series of iterations on an approach for identifying potentially unusual orders. The CCS-SOM takes into account order sizes, ordering frequency, and ordering pattern, which is consistent with my understanding of the concepts set forth in the DEA regulation.

22.   The CCS-SOM is based on a modified logit regression model ("logit model"), which is a statistical tool used to analyze binary data. The logit model is commonly used in

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[33] CVS-MDLT1-000018670 to CVS-MDLT1-000018674

[34] CVS-MDLT1-000123386 to CVS-MDLT1-000123392, CVS-MDLT1-000114642 to CVS-MDLT1-000114652, CVS-MDLT1-000075541, CVS-MDLT1-000088409, CVS-MDLT1-000088410 to CVS-MDTL1-000088411, CVS-MDLT1-000088412 to CVS-MDLT1-000088433, CVS-MDLT1-000088434 to CVS-MDLT1-000088515, CVS-MDLT1-000088577, CVS-MDLT1-000088578, CVS-MDLT1-000088726 to CVS-MDLT1-000088729, CVS-MDLT1-000111189 to CVS-MDLT1-000111190, CVS-MDLT1-000111191 to CVS-MDLT1-000111200, CVS-MDLT1-000111210 to CVS-MDLT1-000111218, CVS-MDLT1-000111219 to CVS-MDLT1-000111227, CVS-MDLT1-000111228 to CVS-MDLT1-000111236, CVS-MDLT1-000111257 to CVS-MDLT1-000111259, CVS-MDLT1-000111260 to CVS-MDLT1-000111262, CVS-MDLT1-000111309 to CVS-MDLT1-000111311, CVS-MDLT1-000111435 to CVS-MDLT1-000111437, CVS-MDLT1-000109623 to CVS-MDLT1-000109625, CVS-MDLT1-000088734 to CVS-MDLT1-000088737, CVS-MDLT1-000088523 to CVS-MDLT1-000088524, CVS-MDLT1-000110439 to CVS-MDLT1-000110441.

economics to model the likelihood of a particular outcome. For example, a logit model can be used to estimate the likelihood that a mortgage application is denied and whether that outcome is tied to race.[35] Other applications include how tuition support affects students' decisions to attend college, as well as factors that determine whether a teenager starts smoking, whether a country receives foreign aid, or whether a job applicant is successful.[36] I have regularly used the logit model throughout my career as an applied economist, including loan scoring for purposes of identifying loans that were in compliance with guidelines on behalf of the Department of Justice in its investigations of mortgage fraud.

23.   In a logit model, the binary variable of interest is the dependent variable (*i.e.,* the "Y" variable that we want to explain), and the model quantifies the relationship between the dependent binary variable (*e.g.*, whether an order is deemed to be unusual) on a set of explanatory variables (the "X" variables that are used to explain the outcome).   The standard logit model estimates the likelihood that an order will be found to be unusual upon further evaluation. The estimated coefficients from the logit model can be used to compute the relative likelihood that the order is unusual.

24.   The binary question addressed by the CCS-SOM is whether an order is cleared for shipment or is listed for further evaluation. The CCS-SOM examines shipment data at the pharmacy store level, and it is my understanding that the logit model was

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[35] Stock, J.H. and M.W. Watson, *Introduction to Econometrics*, 3rd ed., Pearson, 2015, pp. 396-397.

[36] Stock and Watson, p. 386.

developed using CVS's data.[37] The CCS-SOM model initially included explanatory variables based on the prior six months' orders, which later was expanded to the prior twelve months' orders.[38]

25.   An initial iteration of the CCS-SOM system was delivered to CVS in December 2008. For each order, a historical data table was created, which included the total amount of the NDC item that a given store had ordered during the prior six months. The CCS-SOM calculated a series of indicator variables (also known as "dummy" variables) and statistics based on historical data. The algorithm calculated six order attributes that incorporated these historical indicator variables and statistics, as well as current order specifications, and the cumulative amount ordered in the current month including the order in question. Each of these order attributes reflects one of the dimensions referenced in the DEA regulation:

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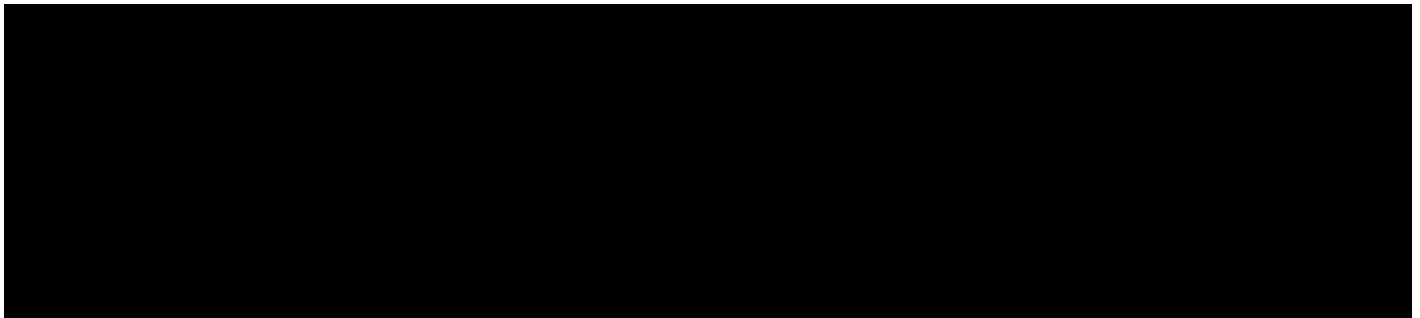
[37] Deposition of Henry John Mortelliti, dated January 23, 2019, Exhibit 615 (CVS-MDLT1-000034183). Exhibit 611 (CVS-MDLT1-000109625). Exhibit 610 (CVS-MDLT1-000114643).
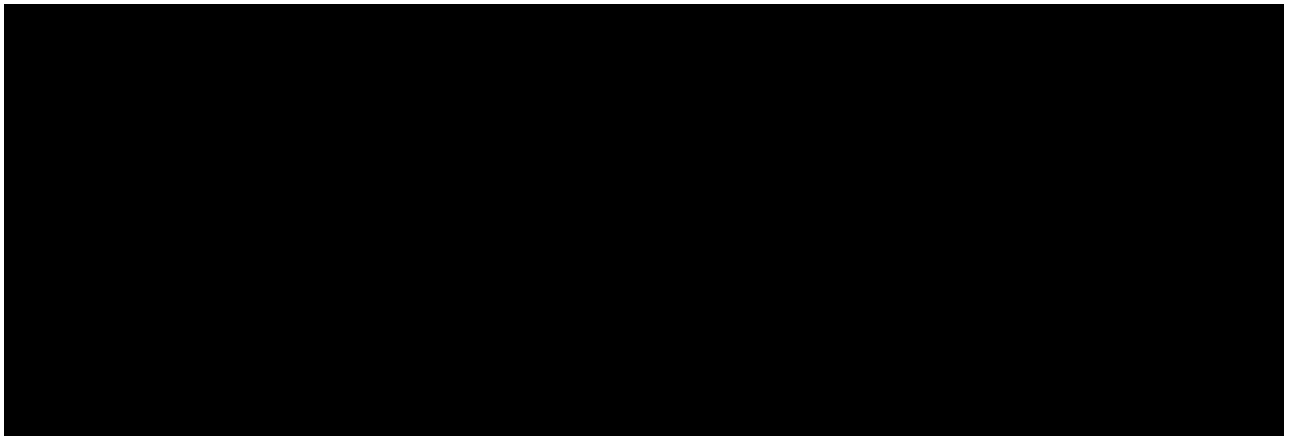
Cegedim Dendrite Descriptive Overview Document: Cegedim Dendrite Suspicious Order Monitoring (SOM) Model, p. 7 (CVS-MDLT1-000123392).
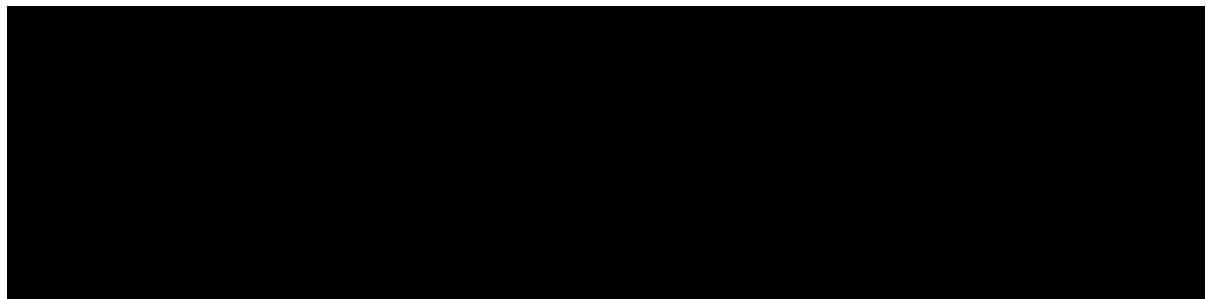
[38] CVS-MDLT1-000114644.

[39] CVS-MDLT1-000123389. The attribute is bounded by 5 and -5.

[40] CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute is bounded by 5 and -5.

The CCS-SOM then uses these six attributes to calculate an index for each order using pre-determined regression coefficients supplied by CCS, as shown below.

The resulting statistic, s, in the equation above, is then compared to a predetermined threshold – 0.15 in the first iteration of the CCS-SOM – to determine whether the order should be flagged for further scrutiny.

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[41] CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the last order was within five days.

[42] CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the cumulative order total is greater than the previous month and the slope of the historical ordering is positive.

[43] CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute is classified as an "override attribute" that seeks to reduce the likelihood of false positives.

[44] CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute is classified as an "override attribute" that seeks to reduce the likelihood of false positives.

26.   After several months of usage, CVS staff informed CCS that the model was "pending a large number of orders that were not suspicious on their face and cleared by CVS staff."[45] As CCS noted at the time, this may happen during the initial implementation of a model reliant on static data. CCS re-calculated the logit regression coefficients and delivered updated values to CVS on August 27, 2009.[46] These new coefficients can be seen in the Item Review Report from September 4, 2009.[47] Notwithstanding the recalculation of coefficients, CVS personnel determined the system was still pending a large number of orders that were not deemed to be suspicious. On February 15, 2010, Robert Williamson of CCS, responding to CVS in regards to excess false-positives, stated

> … a superior option would be to raise the magnitude of the score required to pend an order. The score used for pending is currently .15. We recommend that you have your IT staff adjust this score upwards in small increments until you can determine that the pended orders may be suspicious.[48]

Between March 2010 and July 2010, John Mortelliti, along with CVS Field Loss Prevention, reviewed test IRR reports with increasing index thresholds in order to determine an appropriate level and reduce the incidence of too many false positives. On July 2, 2010, Mr. Mortelliti recommended changing the index threshold from 0.15 to 0.65, and he "verified recommendations from field [Loss Prevention personnel]."[49] According to

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[45] CVS-MDLT1-000114642.

[46] CVS-MDLT1-000109623 to CVS-MDLT1-000109625.

[47] CVS-MDLT1-000024949.

[48] CVS-MDLT1-000110441.

[49] CVS-MDLT1-000088411.

an internal memo on August 13, 2010, "the IRR score was eventually adjusted to .65."[50] The earliest IRR that I have seen showing the index threshold change was September 28, 2010.[51]

27. On February 9, 2011, CCS delivered a second iteration of the CCS-SOM system with a revised algorithm and with new attributes.[52] According to CCS, the adjustment – and future adjustments – "afford[ed] an opportunity for the attributes to be reconfirmed to ensure that the most appropriate order information is collected and analyzed in an appropriate manner."[53] Several changes were made to the model:

– inclusion of both a six-month and a twelve-month historical table,

– conversion to milligrams of active ingredients as the quantity variable so that order comparisons are made on the basis of active ingredient rather than distinguished by brand, formula, or package size, and

– specific new attributes to account for an over-inclusion of false-positives.

Consistent with the first iteration, the CSS-SOM calculates a series of indicator variables and statistics based on six-month and now twelve-month historical data. The model relies on nine order attributes, five binary indicators, and four continuous variables, which are calculated incorporating the historical indicator variables and statistics, current order specifications, and the cumulative amount ordered in the current month (including the order in question).
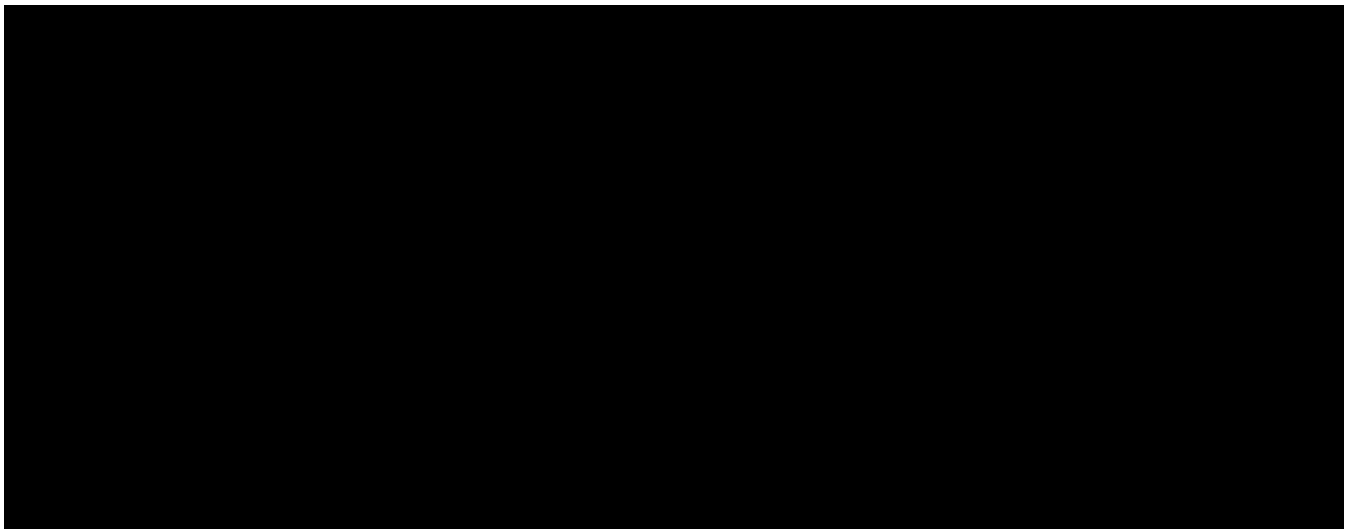
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[50] CVS-MDLT1-000088578.

[51] CVS-MDLT1-000100722 to CVS-MDLT1-000100729

[52] CVS-MDLT1-000114644.

[53] CVS-MDLT1-000114642.

28.   The second iteration of the CCS-SOM system has several improvements over the initial CCS-SOM system. The CCS-SOM system monitors based on milligrams of active ingredient; this is in contrast to the initial CCS-SOM that monitored by product (*i.e.*, Vicodin and not hydrocodone) and also by number of doses (*i.e.*, number of pills). The second iteration measures the volume or quantity by the active ingredient and aggregates that across all products with the same active ingredient. The initial CCS-SOM system applied the same criteria to all orders—that is, the same variables were evaluated using the same coefficients for all orders. The second iteration of the CCS-SOM system evaluated orders from pharmacies that had more frequent orders over the past twelve months differently from orders from pharmacies that had less frequent orders over the past twelve

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[54] CVS-MDLT1-000114650.

[55] CVS-MDLT1-000114650.

[56] CVS-MDLT1-000114650.

[57] CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the cumulative order total is greater than the previous month and the slope of the historical ordering is positive.

[58] CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the last order was within five days.

months.[59] More frequent orders are evaluated using a number of criteria reflecting both six and twelve month historical data and ordering trends whereas less frequent orders are evaluated using twelve month historical data and without trends information.

b) Criticisms by Messrs. Rafalski and Whitelaw of the CCS-SOM are Unfounded

29. I have been asked to focus on certain portions of the Whitelaw and Rafalski Reports that address the CCS-SOM and AGI-SOM. Of the Plaintiffs' Expert Reports that I have referenced and reviewed, Messrs. Whitelaw and Rafalski are the only two who have criticized CVS's SOM systems.

30. Mr. Whitelaw bases his assessment on a "Compliance Maturity & Program Effectiveness Model"[60] and opines that the distributors' compliance programs, including CVS, were inadequate, and he characterized CVS's compliance programs as "remedial."[61] Mr. Whitelaw writes he understands that the CCS-SOM method sought "to apply statistical techniques to establish 'norms' and 'deviations' in order that the overall 'suspiciousness' of the order [could] be evaluated," therefore "[a]t its core, the system [used] a heavily modified

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[59] Deposition of Henry John Mortelliti, dated January 23, 2019, Exhibit 610, (CVS-MDLT1-000109625).

Cegedim Dendrite Descriptive Overview Document: Cegedim Dendrite Suspicious Order Monitoring (SOM) Model (CVS-MDLT1-000114650-51).

CVS-MDLT1-000123389-90, CVS-MDLT1-000123389-92.

[60] Whitelaw Report, p. 43. Though Dr. Whitelaw describes it as the "best approximation of a standardized scoring model" of compliance effectiveness, he provides no evidence that this approach is a generally accepted practice, nor does he explicitly cite to any literature to support his methodology.

[61] Whitelaw Report, p. 161.

logistic regression model."[62]   In addition, according to Mr. Whitelaw, "[t]he model [was] designed so that any order with a score of 0.15 or higher is identified as suspicious, pended, and should be investigated further."[63]

31.   Mr. Whitelaw does not address nor offer any substantive criticisms of the underlying statistical methodology of the CCS-SOM. Rather, Mr. Whitelaw's objections appear to be limited to CVS's decisions to calibrate the CCS-SOM. For example, he criticizes CVS's decision to modify its screening procedures in light of "the mounting problem that the new system was flagging large numbers of orders."[64] According to Mr. Whitelaw, the "CVS solution was to 'tweak' the CCS-SOMs system to flag orders at a manageable level."[65] He adds that "CVS simply altered the system to force the desired outcome even though doing so compromised the effectiveness of the CCS-SOMS program."[66] Mr. Whitelaw does not explain how modifications to the CCS-SOM system "compromised"[67] its effectiveness, nor is there any reason in my opinion that it did.

32.   Mr. Rafalski concludes there was a failure on the part of Defendant Manufacturers and Distributors "to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market."[68] This "systematic failure,"

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[62] Whitelaw Report, p. 173.

[63] Whitelaw Report, p. 173, citing CVS-MDLT1-000114642.

[64] Whitelaw Report, p. 175.

[65] Whitelaw Report, p. 175.

[66] Whitelaw Report, p. 175.

[67] Whitelaw Report, p. 175.

[68] Rafalski Report, p. 7.

according to Mr. Rafalski, "was *a substantial cause* of the opioid epidemic plaguing the country and specifically in Cuyahoga County and Summit County."[69] [emphasis added] Mr. Rafalski, however, does not explain how or why he reached a conclusion of causation, nor does he follow any recognized methodology for establishing causal effects. He appears to rely on the observation of what he believes to be a "failure … to maintain effective controls against diversion" related to an increase in overall shipments of opioids. However, it is improper to equate diversion with shipment amounts, as the two are distinct. Moreover, Mr. Rafalski has not presented an opinion on the amount of diversion that was caused by the supposed deficiencies in CVS's SOMs.   Simply pointing to the shipments presented in the McCann Report does not show excess shipments caused by the supposed deficiencies in CVS's SOMs.

33.	Mr. Rafalski, similar to Mr. Whitelaw, does not provide a criticism of the statistical approach that underpins the CCS-SOM. Mr. Rafalski notes that "there are many other algorithms a distributor could use to identify opioid orders as suspicious."[70] He appears to endorse the model put forward in *Masters Pharmaceutical* despite the fact that it "does not take into consideration unusual pattern or frequency,"[71] while at the same time he ignores without any stated basis the CCS-SOM, which does consider order patterns and frequency in addition to size.

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[69] Rafalski Report, p. 7.

[70] Rafalski Report, footnote 14.

[71] Rafalski Report, p. 46.

34.   Mr. Rafalski, similar to Mr. Whitelaw, criticizes CVS's calibration of the CCS-SOM. According to Mr. Rafalski, between June 2010 and August 2010, Mr. Mortelliti "adjusted the IRR pend score from .15 to .65,"[72] and a few months later, the CCS-SOM "algorithm was delivered to CVS with another set of co-efficients."[73] It is unclear how Mr. Rafalski arrived at this conclusion. Based on a review of the IRRs, a score of 0.65 was used continuously throughout the period leading to the February 2011 adjustment and thereafter.

35.   Neither Mr. Whitelaw nor Mr. Rafalski appears to have expertise or qualifications in statistics. Moreover, they offer only superficial summaries of the underlying statistics, if at all, of the CCS-SOM and AGI-SOM. They do not provide any statistical basis as to why they believe the CCS-SOM and AGI-SOM are improper. Prof. Cutler and Dr. McCann do not provide an opinion on the CCS-SOM or AGI-SOM. I also reviewed the expert reports submitted by Jonathan Gruber,[74] Thomas McGuire,[75] and Meredith Rosenthal,[76] and they also do not provide an opinion on the CCS-SOM or AGI-SOM. Accordingly, based on my review of Plaintiffs' experts reports — collectively, they either have no opinion or no objections to the underlying statistical methods of the CCS-SOM or AGI-SOM.

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[72] Rafalski Report, p. 107.

[73] Rafalski Report, p. 107.

[74] "Expert Report of Professor Jonathan Gruber," dated March 25, 2019 ("Gruber Report").

[75] "Expert Report of Professor Thomas McGuire: Damages to Bellwethers," dated March 25, 2019 ("McGuire Report") and "Expert Report of Professor Thomas McGuire Regarding Public Nuisance," dated March 25, 2019 ("McGuire Nuisance Report").

[76] "Expert Report of Professor Meredith Rosenthal," dated March 25, 2019 ("Rosenthal Report").

36.   The non-statistical criticism of the calibration is not well-founded. It is common and appropriate to calibrate statistical models (as CVS has done), and it is economically sensible to minimize false positives to a reasonable degree. Mr. Whitelaw does not countenance the fact that CVS had legitimate reasons to calibrate the CCS-SOM. In fact, as noted by CCS in the February 9, 2011, CCS-SOM Retunement document:

> "The 'retunement' event is a recommended practice to review and possibly re-adjust the SOM model coefficients for optimum sensitively. As noted above this may be necessary since the model is developed using historical data that is provided at the start of the design and ordering habits may naturally evolve and change over time … The yearly adjustment also affords an opportunity for the attributes to be reconfirmed to ensure that the most appropriate order information is collected and analyzed in an appropriate manner."[77]

Indeed, I understand that CVS engaged in a process of evaluating orders that were flagged by the CCS-SOM, and had determined that the initial parameter was generating an excess number of false positives. Moreover, the recalibration by CVS was not an arbitrary process but a deliberative one based on recommendations from CCS to reduce the incidence of false positives down to a reasonable level and in consultation with field personnel, who shared their insights and experiences dealing with false positives. From a statistical standpoint, reducing the number of false positives is desirable and would not "compromise the effectiveness" of the CCS-SOM.

37.   Messrs. Rafalski and Whitelaw also put forward unsubstantiated and improper characterizations of CVS's decision to calibrate the CCS-SOM. Mr. Whitelaw, as

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[77] CVS-MDLTl-000114642.

an example, states that the calibrations were designed to generate "pre-ordained outcomes."[78] Mr. Whitelaw's characterization regarding CVS's motives for calibrating the CCS-SOM is inconsistent with his other assertion that CVS did not investigate flagged orders. The latter assertion also is inconsistent with the testimony of Mr. Mortelliti who worked to reduce false positives because of the complaints from Field Loss Prevention personnel forced to review so many false positives.[79] If CVS was not evaluating flagged orders, then there would be no point in CVS expending time and resources to calibrate the CCS-SOM.

38.   Equating calibration of a model with improper motivations reveals a lack of understanding of statistical methods and the fact that calibration is common. It is common practice to calibrate statistical models, particularly if the aim is to improve prediction accuracy as is the case for SOM models.[80]

39.   As Mr. Rafalski states, "there are many other algorithms a distributor could use to identify opioid orders as suspicious."[81] Mr. Rafalski, however, provides no basis for his criticisms of the CCS-SOM. Moreover, Mr. Rafalski does not justify his endorsement of the algorithms applied in the McCann Report; his endorsement is not grounded in accepted statistical methods. Similarly, in one instance Mr. Whitelaw refers to the CCS-SOM as

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[78] Whitelaw Report, p. 172.

[79] Deposition of Henry John Mortelliti, dated January 23, 2019, p. 292:3-16.

[80] "Once the forecasts are developed, the forecasted sales should be compared on a regular basis to actual sales to see whether some type of corrective action is needed." Kress, G.J. and J. Snyder. *Forecasting and Market Analysis Techniques: A Practical Approach.* Quorum Books, 1994, p.201.

[81] Rafalski Report, p. 10, footnote 14.

"remedial" and is critical of CVS calibrating the CCS-SOM.[82] However, he seems to ignore (or be unaware of) the fact that the CCS-SOM applies an accepted statistical technique of a logit model and is consistent with CSA objectives.

D.   **Analysis Group SOM ("AGI-SOM")**

   a)   **The AGI-SOM Applies Established Statistical Methods and is Consistent with DEA criteria**

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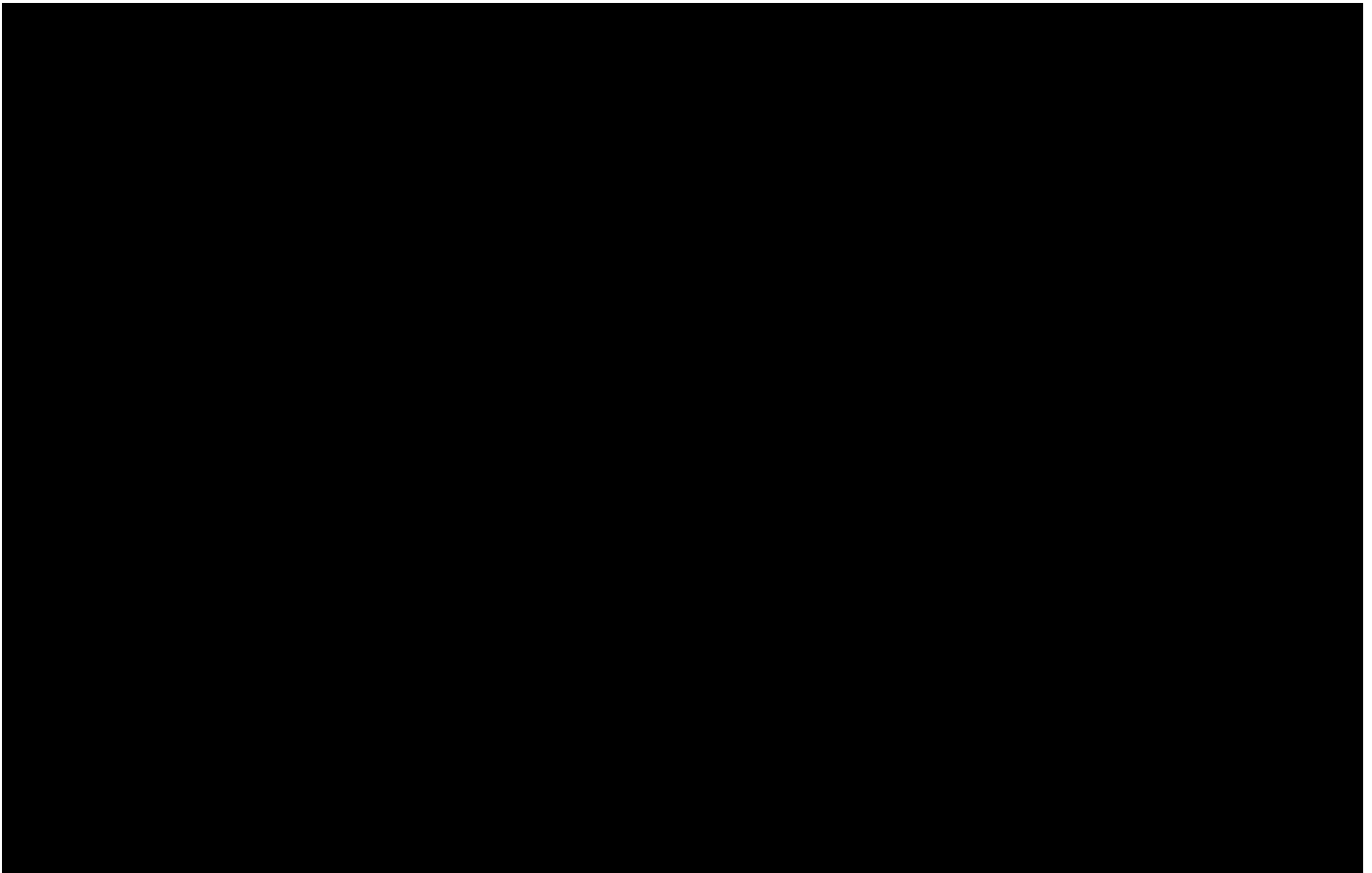
[82] Whitelaw Report, pp. 161, 175.

[83] Krzywinski, Martin, and Naomi Altman. "Points of significance: visualizing samples with box plots," *Nature Methods*, volume 11, pp. 119-120 (2014).

V. Response to Dr. McCann's Analysis

A. Summary of Dr. McCann's Analysis

42.   I have been asked to provide an opinion on Sections IX and X of the McCann Report and parts of the corresponding portions of the McCann Supplemental Report. Also, since Mr. Rafalski has endorsed the methodologies in the McCann Report as proper methods to identify suspicious orders that were undetected by CVS, my response is also to Mr. Rafalski. In Section IX, Dr. McCann identifies transactions in the ARCOS data "meeting specified criteria,"[85] ostensibly to determine whether orders are "excessive." In Section X, Dr. McCann quantifies the number of "excessive shipments" to Cuyahoga and Summit counties based on what he asserts are "medically necessary" opioid shipments.[86]

43.   The McCann Report applies "certain algorithms to the ARCOS data,"[87] and identifies "transactions meeting specified criteria"[88] in the section of the McCann Report

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[84] DuToit, Stephen HC, A. Gert W. Steyn, and Rolf H. Stumpf. *Graphical exploratory data analysis*. Springer Science & Business Media, 2012, p. 29.

[85] McCann Report, ¶130.

[86] McCann Report, ¶¶155-156

[87] McCann Report, ¶12.

titled "Transaction Analysis."[89] Dr. McCann adopts five methodologies (or algorithms) to flag orders, each of which examines order size but ignores the other two dimensions of the DEA criteria, namely order frequency and pattern:

1) Transactions that exceed the maximum shipped dosage units in any of the preceding six months.

2) Transactions that exceed twice the trailing twelve-month average dosage units.

3) Transactions that exceed three times the trailing twelve-month average dosage units.

4) Transactions that "cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units."

5) Transactions that "cause the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation."

The first three methodologies consider past shipping volumes to determine the threshold for flagging orders that warrant further scrutiny. As a result, these first three methodologies indirectly take into account factors such as pharmacy size, *i.e.,* whether a pharmacy serves a larger community and thus has a history of ordering larger volumes. In contrast, the fourth and fifth methodologies rely on pre-set thresholds that do not take into account any aspects that may reflect legitimate demand for opioids. For these last two methodologies to be relevant to the task of detecting potentially suspicious orders, the thresholds need to be justified on a case by case basis to determine that they are

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[88] McCann Report, ¶56.

[89] McCann Report, ¶¶130-152.

appropriate to detect potentially unusual shipments for a given pharmacy and drug. Neither of the two takes into account potential differences between pharmacies.

44.   Dr. McCann also assumes, at Plaintiffs' counsel's request, that if an order is flagged and "not effectively investigate[d], … every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction."[90] Dr. McCann does not establish what "effectively investigated" means, nor does he express any opinion that orders were not effectively investigated.

45.   Dr. McCann calculates what he deems to be "excessive shipments" by assuming an upper and a lower bound for "medically necessary opioid MME per capita."[91] The McCann Supplemental Report presents additional figures and tables which "were overlooked in the preparation of the McCann Report [and] do not in any way alter the conclusions" of the McCann Report.[92]

B.   Dr. McCann's Analyses are Not Relevant to Assessing the Effectiveness of CVS's SOM Algorithms

46.   Dr. McCann does not examine the appropriateness or suitability of CVS's SOM systems. Rather, he "[applies] certain algorithms to the augmented ARCOS Data"[93] without providing any substantive support as to why he has elected to adopt these

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[90] McCann Report, ¶132.

[91] McCann Report, ¶155.

[92] McCann Supplemental Report, ¶5.

[93] McCann Report, ¶12.

algorithms. I understand Dr. McCann applies an algorithm similar to one employed in *Masters Pharmaceutical*,[94] as well as methodologies analogous to those implemented by some of the other Defendants. However, he provides no basis in the facts of the case for applying these algorithms. Dr. McCann also does not indicate how his analysis is relevant or of use to the fact finder. The guidance provided by the DEA and in the CFR does not prescribe any specific SOM algorithm, and neither Dr. McCann nor Mr. Rafalski clarifies if or why the algorithms he employed are superior to the ones employed by CVS, nor demonstrate that they provide a preferable measure for a but-for scenario.

47.   Dr. McCann does not claim whether the objective of applying these algorithms to the transaction data is to identify suspicious orders consistent with the DEA. He presents no references to peer-reviewed or published economics or statistics literature to support these methodologies. Similarly, he does not discuss whether these methodologies are an appropriate way of identifying potentially suspicious orders, or why these methodologies are preferable over other techniques.

C.   Dr. McCann's Algorithms Do Not Reflect the Criteria Identified in the SOM Regulation

48.   Dr. McCann's adoption of the "unfulfilled obligation" assumption further eliminates any semblance his algorithms may have had to the DEA criteria. The DEA criteria are aimed at identifying potentially unusual orders, but the "unfulfilled obligation"

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[94] Rafalski Report, p. 46. Mr. Rafalski also notes that this approach does not control for unusual pattern or frequency

assumption means that orders are flagged irrespective of whether they are potentially unusual: once an order is flagged, all subsequent orders for the corresponding drug code/pharmacy pair are flagged.

49.   Over time, the assumption results in one of two scenarios for a drug code/pharmacy pair: (1) no orders are flagged, or (2) all orders are flagged from a certain point in time. If Plaintiffs' argument is that in the but-for world CVS would have more thoroughly investigated suspicious orders before shipping them, then it is not plausible to postulate that in this particular scenario CVS would have stopped all shipments to a pharmacy once an order is flagged as suspicious and requiring further scrutiny. Moreover, it is my understanding that *Masters Pharmaceutical* did not sanction flagging every subsequent order.

50.   As a result, Dr. McCann's methodologies provide an unrealistic and improper criterion for identifying orders for due diligence: at a pharmacy-drug code level either no orders are flagged or all orders are flagged. For example, if a HCP order is flagged according to Dr. McCann's trailing six-month maximum threshold algorithm in April 2003, every HCP order – regardless of if it would trigger the threshold on its own – is flagged, potentially years after the initial flagged order.

51.   To illustrate the effect of the "unfulfilled obligation" assumption adopted by Dr. McCann, I replicated Dr. McCann's methodologies but without the "unfulfilled obligation" assumption to demonstrate the impact of Plaintiffs' counsel's instructions. It is summarized in the charts below.

% Flagged: Comparison of Dr. McCann's Methodologies with and without the "Unfulfilled Obligation" Assumption (Cuyahoga and Summit)
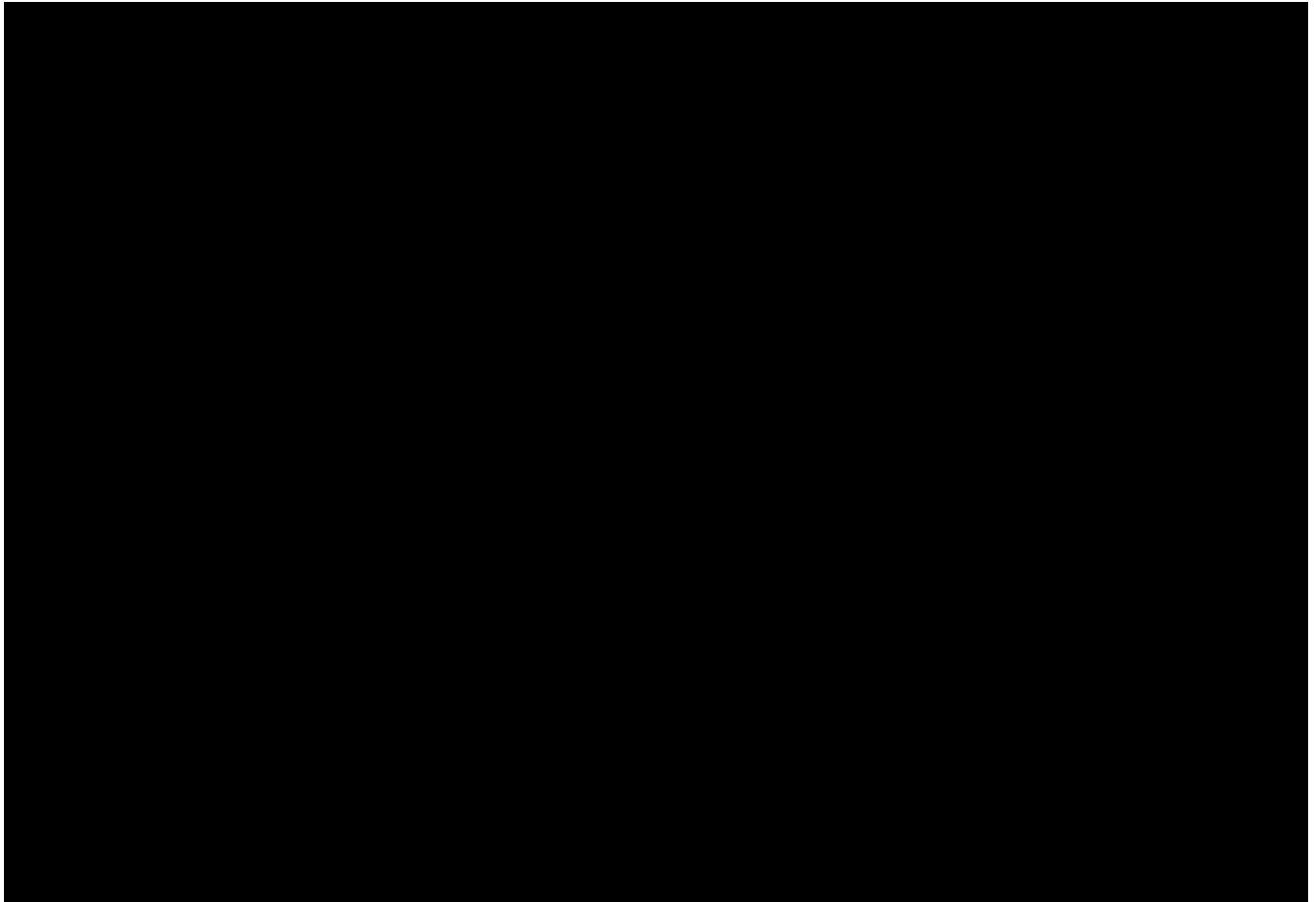
52.   For each of Dr. McCann's five methodologies, I show in the charts above the percent of flagged MMEs as a percent of total MMEs shipped by CVS into the Counties of Cuyahoga and Summit with and without the "unfulfilled obligation" assumption for HCP. The difference is drastic, particularly for the first three methodologies, which consider past shipping volumes.   According to Dr. McCann's first algorithm, which Prof. Cutler

purportedly relies upon, 100% of the MMEs shipped by CVS were illegitimate from 2004 on, except for a period in 2006 and 2010, which are not 100% due to Dr. McCann's programmatic choices.[95]   However, when the "unfulfilled obligation" assumption is removed, the first methodology results in very low percentages. The last two methodologies are not as sensitive to the "unfulfilled obligation" assumption; however, they are not good methods of detecting outliers because they are based on a fixed threshold, which fails to take into account other relevant factors, such as a store's size, ordering pattern, and frequency of orders.

D.   Dr. McCann's Assumptions on Third-Party Distributors

53.   Dr. McCann also was asked to "assume that Chain Distributors may have had knowledge of – or information available to inform them of – opioid shipments from all Distributors to the Chain Distributor's affiliated pharmacies."[96]   He then re-ran the algorithms with this assumption. Dr. McCann, however, does not provide any check as to whether this assumption is accurate. Moreover, it is unclear what the purpose of this exercise is considering none of the other Plaintiffs' experts appear to rely upon this particular analysis, and, as I understand it a registrant does not have an obligation to review orders it does not ship to determine whether they are of unusual size, frequency or pattern..

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[95] Dr. McCann tested based on DEA number, and did not combined identical stores. This decision causes the flagging to restart when the DEA number switches in the data, which temporarily lowers the percentage.

[96] McCann Report, ¶152.

VI.   Cutler Report

54.   I have been asked to address only certain portions of the Cutler Report, as they pertain to Prof. Cutler's reliance on Dr. McCann.   The Cutler Report provides an estimate of the share of harms attributable to distributor conduct.[97]

Share of Harms Attributable to Distributor Misconduct
= (Share of Harms Attributable to Opioids)
× (Share of Opioid Harms Attributable to Opioid Shipments)
× (Share of Opioid Shipments Due to Distributor Misconduct)

Prof. Cutler estimates the share of harms attributable to opioids using a variety of sources, including the Cuyahoga Prosecutor Database, the FBI's National Incident-Based Reporting System ("NIBRS"), and the National Survey on Drug Use and Health ("NSDUH").   To quantify the share of opioid harms attributable to opioid shipments, he conducts regression analyses.   For the share of opioid shipments due to distributor misconduct, Prof. Cutler refers to Table J.1, which Prof. Cutler attributes to Dr. McCann.[98] As I previously stated, it is unclear if Dr. McCann provided those specific estimates of the shipments.

55.   Even if the shipment figures ultimately did come from Dr. McCann, Prof. Cutler has misapplied Dr. McCann's shipment figures.   In contrast to Mr. Rafalski, who stated that the methodologies applied by Dr. McCann "was to identify suspicious orders that should not be shipped *unless* the distributors' due diligence eliminated the suspicion of diversion,"[99] (emphasis added) Prof. Cutler appears to have adopted Dr. McCann's analysis

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[97] Cutler Report, Appendix J.

[98] Deposition of Dr. David Cutler dated April 26, 2019, p.81:11-17.

[99] Rafalski Report, page 41.

as measuring the "percent of shipments attributable to distributors' misconduct."[100] Prof. Cutler's interpretation appears to be incorrect and has the effect of grossly inflating the number of shipments used to attribute damages to distributors' alleged misconduct.

56.   As I previously discussed, it appears that Prof. Cutler has applied Dr. McCann's first algorithm.[101] However, Dr. McCann's first algorithm yields unrealistic and unreasonable estimates of flagged shipments for CVS, in many instances 100% of shipments, which is entirely due to Dr. McCann's adoption of the "unfulfilled obligation" assumption. There has been no justification provided for this assumption by Dr. McCann. Moreover, when this assumption is removed, the number of flagged shipments for CVS drops considerably to, in many instances, relatively negligible amounts. Accordingly, it is my opinion that Prof. Cutler has applied an incorrect measure for flagged shipments. However, given the lack of reconciliation between Prof. Cutler and Dr. McCann, I reserve the right to amend my comments should it be the case that Prof. Cutler relied on a different methodology.

VII. Conclusions

57.   CVS had in place SOMs throughout the damages period. I have reviewed the CCS-SOM and AGI-SOM. Although they are different statistical methods, they both apply

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[100] Cutler Report, Table J.1.

[101] I understand Table A in the McCann Supplemental Report is the source for Table J.1 in the Cutler Report. The title for Table A in the McCann Supplemental Report is "Trailing Six-Month Maximum Threshold Flagged Transactions."

established statistical methods for identifying outliers. Moreover, both SOMs appear to be consistent with DEA requirements and are reasonable models to detect potential outliers. The fact that CVS calibrated the CCS-SOM was appropriate; it is common to calibrate statistical models, particularly when the goal is accuracy and the reduction of false positives.

58.   Messrs. Rafalski and Whitelaw do not provide any basis grounded in statistics, an area in which neither has documented experience or training, to disregard entirely SOMs that CVS paid to have developed and had in place from 2008 through 2014, when it stopped distributing HCPs. In criticizing the CCS-SOM, Mr. Rafalski simply claims that it should be replaced by methodologies put forward by Dr. McCann. There is no basis provided by Mr. Rafalski as to why these methodologies are more appropriate, particularly since they do not appear to be consistent with DEA regulations.

59.   Based on my assessment of Dr. McCann's methodologies, they are unreasonable methods, reliant on an extreme assumption, that do not reflect proper economic analysis or common sense. Simply removing the unsupported "unfulfilled obligation" assumption drastically reduces the number of flagged orders.

60.   Finally, it is unclear as to whether Prof. Cutler properly adopted Dr. McCann's shipment numbers. Prof. Cutler acknowledged that the figures were from Dr. McCann.[102] However, to date, I have been unable to reconcile figures in the McCann Report with the figures Prof. Cutler claim come from Dr. McCann. Prof. Cutler has testified that

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[102] Deposition of David Cutler, Ph.D., dated April 26th, 2019, p. 80:5-8.

the numbers in Table J .1 were provided to him by Plaintiffs' counsel,[103] and that he is not providing an opinion about whether the numbers in Table J.1 are correct.[104] In fact, Prof. Cutler testified that he had not looked at the McCann Report or the McCann Supplemental Report,[105] nor talked to Dr. McCann about the analysis in the report.[106] He also testified that he did not know how the numbers in Table J.l had been calculated.[107]

William S. Choi, Ph.D.
May 10, 2019

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[103] Deposition of David Cutler, Ph.D., dated April 26th, 2019, p. 80:5-8.

[104] Deposition of David Cutler, Ph.D., dated April 26th, 2019, pp. 81:24-84:22.

[105] Deposition of David Cutler, Ph.D., dated April 27th, 2019, pp. 594:19-595:3.

[106] Deposition of David Cutler, Ph.D., dated April 26th, 2019, pp. 114:19-115:17.

[107] Deposition of David Cutler, Ph.D., dated April 26th, 2019, p. 86:14-15; Deposition of David Cutler, Ph.D., dated April 27th, 2019, pp. 596:2-597:24.